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VIA ECF

Honorable Stanley R. Chesler, U.S.D.J.
United States District Court
District of New Jersey
U.S. Post Office & Courthouse Building
Federal Square
Newark, New Jersey 07101

Re: Bausch Health Companies Inc. f/k/a Valeant Pharmaceuticals International, Inc., et al. v. Mylan Pharmaceuticals, Inc., et al., Civil Action No. 15-8180 (SRC) (CLW) (CONSOLIDATED)

Dear Judge Chesler:

This firm represents Plaintiff Wyeth LLC and, along with Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, represents Plaintiffs Bausch Health Companies Inc. f/k/a Valeant Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc., and Progenics Pharmaceuticals, Inc. (collectively, “Plaintiffs”), in the above-referenced actions. We write in response to Mylan’s letter (ECF No. 417) to correct Mylan’s continued mischaracterization of the Federal Circuit’s holding. To accept paragraph three in Mylan’s proposed order would prejudicially deprive Plaintiffs of due process because it would amount to a ruling of *prima facie* obviousness for Mylan without allowing Plaintiffs to establish a fair and complete record in this Court.

Mylan alleges that Plaintiffs’ assertions are unfounded and that Plaintiffs are purportedly ignoring the Federal Circuit’s statement agreeing “with Mylan that the **record** supports a *prima facie* case of obviousness **here**.¹” (See ECF No. 417 at 1-2.) The operative words are “record” and “here,” for Mylan knows, as did the Federal Circuit, that the summary judgment record on appeal was limited and far short of the full amount of evidence that will go in at trial to assess, for example, whether the prior art gave rise to a *prima facie* case of obviousness. But Mylan is tactically seeking to have this Court enter an Order that a *prima facie* case of obviousness has been established, as if it were a “fait accompli”¹ to improperly shift to Plaintiffs the burden of coming forward with objective evidence of non-obviousness. See *In re Cyclobenzaprine*, 676 F.3d 1063, 1079-80 (Fed. Cir. 2012) (referring to the improper burden shifting within the obviousness framework).

The narrow record before the Court on summary judgment was based **only** on the admissions and testimony of Mylan’s experts. Plaintiffs did not affirmatively rely on **any** evidence from their own experts in their summary judgment briefing. It is completely unreasonable for

¹ Mylan did not even try to qualify its proposed provision regarding the *prima facie* case consistent with the record on appeal and the Federal Circuit’s decision, for it knows that to do so would equitably require it to load the provision with numerous conditions and caveats, making the provision meaningless and actually highlighting its absurdity.

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Mylan to even suggest that it has established a *prima facie* case of obviousness when this Court has not considered any evidence from Plaintiffs' experts regarding the teachings of the prior art. As held by the Federal Circuit, Mylan has merely survived summary judgment on a limited record, a record lacking any evidence from Plaintiffs' experts. (ECF No. 406 at 13-14 (explaining that "Mylan had raised a *prima facie sufficient to survive summary judgment.*"') (emphasis added).)

The Federal Circuit further stated in this regard that its holding should not be misconstrued, ultimately guiding the parties and this Court that "[w]hether methylnaltrexone's structural similarity in an overlapping range of pH in solution *is sufficient to yield a prima facie case* of obviousness *depends on the facts of record.*"² (ECF No. 406 at 14.) This statement alone shows that by simply escaping summary judgment Mylan has not established a *prima facie* case of obviousness. Indeed, the Federal Circuit stated that Plaintiffs may proffer evidence, for example, "that the prior art teaches away from the claim invention in any respect." *Id.* Evidence of teaching away fundamentally goes to whether a *prima facie* case of obviousness exists (or not), for it can bear directly on whether a person of ordinary skill in the art would have been motivated to combine references and/or whether a reasonable expectation of success would have existed. *See, Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018) (finding that teaching away can negate a purported motivation to combine references).

Mylan's mischaracterization of the Federal Circuit's holding in its proposed order is nothing more than an attempt to improperly shift the burden to Plaintiffs heading into trial to secure an advantage it has not earned. Therefore, for at least these reasons, we respectfully request that the Court strike paragraph three of the proposed order before executing and filing it on the docket.

We thank the Court for its attention and consideration of this matter. Plaintiffs are available to discuss this issue with Your Honor should Your Honor require any further information.

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

cc: All counsel of record (via ECF)

² Tellingly, in support of this proposition, the Federal Circuit cited *In re Jones*, 958 F.2d 347, 350 (Fed. Cir. 1992), noting that "[e]very case, particularly those raising the issue of obviousness under section 103, must necessarily be decided upon its own facts"—facts and a record, which everyone knows, has not yet been fully established.